

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

1600 Ninth Street, Room 432
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AGENDA
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
HEALTH AND HUMAN SERVICES AGENCY
1600 9th Street, Room 470
Sacramento, CA 95814

Friday, August 6, 2004
9:00 am – 5:00 pm

A. Announcements and Policy Discussion:

1. FDA audit
2. Process for Expedited Review confirmation by CPHS staff
3. Review process for OSHPD data requests
4. Revised internal review forms
5. Definition of small cell size
6. Definition of subject population for CPHS review
7. Deferral to CDC IRB
8. Web site revisions, logo, and redesign update
9. PI Attendance and Call List

B. Approval of minutes from the June 4, 2004 meeting

C. Continuing Review Calendar

Continuing Review – With Revisions

1. Project No. 98-08-12 (Mihordin)

Project Title: "Production of Human Botulism Immune Globulin"

Principal Investigator: Stephen S. Arnon, MD
DHS
Richmond, CA

2. Project No. 02-08-06 (Lowe)

Project Title: "California CADDRE: Access to Records of Patients from Clinics and Private Providers"

Principal Investigator: Judith Grether, PhD
DHS
Oakland, CA

Review of Revisions Only

3. Project No. 94-04-11 (Murphy)

Project Title: "Molecular Epidemiology of Childhood Leukemia"

Principal Investigator: Peggy Reynolds, PhD
DHS
Oakland, CA

73. Project No. 01-12-15 (Mihordin)

Project Title: "Assessment of Mental Illness, Violence Risk and Readiness for Release in a Forensic Facility"

Principal Investigator: Barbara McDermott, PhD
UC Davis-Napa Psychiatric Research Center
Napa, CA

Continuing Review/No Revisions – Expedited Review

4. Project No. 03-08-01 (Lowe) **APPROVED**

Project Title: "California Student Survey, 2003-04"

Principal Investigator: Gregory Austin, PhD
WestEd
Los Alamitos, CA

5. Project No. 01-08-05 (Lowe) **APPROVED**

Project Title: "California Student Survey, 2001-02"

Principal Investigator: Gregory Austin, PhD
WestEd
Los Alamitos, CA

6. Project No. 01-08-20 (Murphy)

Project Title: "Prevalence of Dementia and Associated Risk Factors in HIV Positive Prisoners in the Vacaville Correctional

Medical Facility”

Principal Investigator: Joseph Bick, MD
Department of Corrections
Vacaville, CA

7. Project No. 02-08-03 (Mihordin)

Project Title: “Genetic Susceptibility to Hypospadias”
Principal Investigator: Suzan Carmichael, PhD
DHS
Berkeley, CA

8. Project No. 01-08-04 (Mihordin)

Project Title: “HIV-Related Behavioral Surveillance and Seroprevalence
Estimates Among Gay and Bisexual Men in California:
A 2001 California Health Interview Survey Re-interview”

Principal Investigator: Joseph A. Catania, PhD
UCSF
San Francisco, CA

9. Project No. 01-08-02 (Lowe)

Project Title: “Association of Medicaid Status with Late-Stage
Cancer and Validation of Medicaid Status from
the Medical Record”

Principal Investigator: Christina Clarke, PhD
Northern California Cancer Center
Union City, CA

10. Project No. 01-08-01 (Opton)

Project Title: “Indian Health Services and Department of Health
Services Linkage Project”

Principal Investigator: James Allen Crouch, MPH
California Rural Indian Health Board, Inc.
Sacramento, CA

11. Project No. 99-08-01 (Cordero) **APPROVED**

Project Title: “Laboratory Reporting for Pesticide Illness Surveillance”

Principal Investigator: Rupali Das, MD
DHS

Oakland, CA

12. Project No. 02-08-09 (Lowe)

Project Title: "Is There Excess Hospital Mortality on the Weekend?"

Principal Investigator: Carlos Dobkin
UC Berkeley
Berkeley, CA

13. Project No. 03-08-57 (Mihordin)

Project Title: "Evolution of Nef Epitopes in Africans"

Principal Investigator: Richard M. Donovan, PhD
DHS
Richmond, CA

14. Project No. 02-08-11 (Dickey)

Project Title: "Evaluation of California's Supplemental Screening
Research Project for Metabolic Disorders Using Tandem
Mass Spectrometry (MS/MS)"

Principal Investigator: Lisa Feuchtbaum, Dr PH
DHS
Richmond, CA

15. Project No. 01-08-08 (Lubeck) **APPROVED**

Project Title: "Linking Birth Certificate Data to the Southern
California Children's Health Study Cohort Data"

Principal Investigator: Frank Gilliland, MD, PhD
USC Keck School of Medicine
Los Angeles, CA

16. Project No. 98-08-08 (Mihordin)

Project Title: "Ultra-Micro Immunoassay of Newborn Blood Spots for
Remainder of Children in 1983-85 Cerebral Palsy Study"

Principal Investigator: Judith Grether, PhD
DHS
Oakland, CA

17. Project No. 03-08-59 (Lowe) **APPROVED**

Project Title: "Childhood Autism Perinatal Study"

Principal Investigator: Judith Grether, PhD
DHS
Oakland, CA

18. Project No. 03-08-56 (Opton)

Project Title: "HLA in Hispanic and African American Autistic Subjects"

Principal Investigator: Judith Grether, PhD
DHS
Oakland, CA

19. Project No. 03-08-54 (Lowe) **APPROVED**

Project Title: "Investigation of Hazardous Air Pollutants (HAPs)
and Autism Spectrum Disorders"

Principal Investigator: Judith Grether, PhD
DHS
Oakland, CA

20. Project No. 01-08-10 (Murphy)

Project Title: "Alcohol Outlets and Violence"

Principal Investigator: Paul J. Gruenewald, PhD
Prevention Research Center
Berkeley, CA

21. Project No. 82-08-01 (Cordero) **APPROVED**

Project Title: "California Birth Defects Monitoring Program"

Principal Investigator: John Harris, MD, MPH
DHS
Berkeley, CA

22. Project No. 02-06-09 (Opton)

Project Title: "Case-Control Study of Risk Factors for Kawasaki
Disease (KD) Among Children, 2002-2003"

Principal Investigator: Annie S. Kao, MPH
UC San Diego
La Jolla, CA

23. Project No. 98-08-13 (Lowe)

Project Title: "Project Baby's Breath: A Study of Environmental Exposure During Pregnancy"

Principal Investigator: Martin Kharrazi, PhD
DHS
Richmond, CA

24. Project No. 00-08-10 (Cordero)

Project Title: "East Bay Children's Respiratory Health Study: Traffic-Related Air Pollution Near Busy Roads"

Principal Investigator: Janice J. Kim, MD, MPH
Office of Environmental Health Hazard Assessment
Oakland, CA

25. Project No. 02-08-04 (Mihordin) **APPROVED**

Project Title: "Improving Influenza Vaccine Coverage Levels Among Nursing Home Health Care Workers"

Principal Investigator: Akiko Kimura, MD
DHS
Gardena, CA

26. Project No. 01-08-06 (Cordero)

Project Title: "Illegal and Unregulated Medical Care: Prevalence, Knowledge, Attitudes, and Behaviors among Latinos in Los Angeles County"

Principal Investigator: Akiko Kimura, MD
DHS
Gardena, CA

27. Project No. 03-08-51 (Harris) **APPROVED**

Project Title: "Surgical Management of Endometrial Cancer in California"

Principal Investigator: Leiserowitz, MD
UCD
Sacramento, CA

28. Project No. 02-06-08 (Lowe) **APPROVED**

Project Title: "Evaluation of the Substance Abuse and Crime Prevention Act of 2000"

Principal Investigator: Douglas Longshore, PhD
UCLA
Los Angeles, CA

29. Project No. 01-08-13 (Dickey)

Project Title: "A Pilot Project for the Assessment and Evaluation of
Tandem Mass Spectrometry (MS/MS) for Detection of
Inborn Errors of Metabolism during the Newborn Period"

Principal Investigator: Fred Lorey, PhD
DHS
Berkeley, CA

30. Project No. 90-08-14 (Opton)

Project Title: "A Registry of California-born Twins"

Principal Investigator: Thomas Mack, MD, MPH
USC Keck School of Medicine
Los Angeles, CA

31. Project No. 00-08-05 (Cordero)

Project Title: "Surveillance of Occupational Lead Poisoning"

Principal Investigator: Barbara Materna, PhD
DHS
Oakland, CA

32. Project No. 97-08-05 (Cordero) **APPROVED**

Project Title: "Linked Maternal-Infant Medical Record Surveillance
RFA 96-27028"

Principal Investigator: Yvonne Maldonado, MD
Stanford University School of Medicine
Stanford, CA

33. Project No. 01-08-14 (Murphy)

Project Title: "In-School Evaluation of Tobacco Use Prevention
Education Programs"

Principal Investigator: William McCarthy, PhD
WestED
Los Angeles, CA

34. Project No. 03-08-02 (Murphy)

Project Title: "In-School Evaluation of Tobacco Use Prevention Education (TUPE) Programs, 2003-2004"

Principal Investigator: William McCarthy, PhD
WestED
Los Angeles, CA

35. Project No. 00-08-06 (Lowe) **APPROVED**

Project Title: "Language Acquisition in Infants and Children"

Principal Investigator: Toben H. Mintz, PhD
USC
Los Angeles, CA

36. Project No. 02-08-08 (Lowe)

Project Title: "Cash Assistance Dispersement and Health Outcomes"

Principal Investigator: Steve Puller, PhD
Texas A&M University
College Station, TX

37. Project No. 00-08-01 (Murphy)

Project Title: "Ultra-Micro Immunochemistry Analysis of Newborn Blood Spots for Childhood Onset Schizophrenia (COS): A Pilot Study"

Principal Investigator: Judith Rapoport, MD
National Institute of Mental Health
Bethesda, MD

38. Project No. 95-08-03 (Opton)

Project Title: "Childhood Cancer-Etiologic Clues Using Geographic Information Systems"

Principal Investigator: Peggy Reynolds, PhD
DHS
Oakland, CA

39. Project No. 96-08-08 (Lowe) **APPROVED**

Project Title: "The Influence of Air Pollution in the Los Angeles Metropolitan Area on the Occurrence of Birth Defects"

Principal Investigator: Beate Ritz, MD, PhD
UCLA

Los Angeles, CA

40. Project No. 99-08-13 (Harris) **APPROVED**

Project Title: "HIV Prevalence, Incidence, and Risk Behaviors Among Young Latino Men Who Have Sex with Men in San Diego, California, and Tijuana, Mexico"

Principal Investigator: Juan Ruiz, MD, Dr PH
DHS
Sacramento, CA

41. Project No. 01-08-03 (Mihordin)

Project Title: "Prenatal Diagnosis of Smith-Lemli-Opitz Syndrome"

Principal Investigator: Marie Roberson, PhD
DHS
Berkeley, CA

42. Project No. 96-08-02 (Murphy)

Project Title: "Kawasaki Disease – archive for Etiological Testing"

Principal Investigator: Robert Schechter, MD
DHS
Berkeley, CA

43. Project No. 96-08-05 (Harris) **APPROVED**

Project Title: "Obesity Gene Variants and Neural Tube Defects"

Principal Investigator: Gary M. Shaw, Dr PH
DHS CA Birth Defects Monitoring Program
Berkeley, CA

44. Project No. 01-08-07 (Opton)

Project Title: "Community Geographic Information System Project"

Principal Investigator: Don Taylor, MA
California Children and Families Commission
Sacramento, CA

45. Project No. 98-08-03 (Murphy)

Project Title: "Maternal Age-Specific Prevalence Rates of Chromosome Abnormalities by Race/Ethnicity in the Kaiser Health Plan"

in Northern and Southern California and Portland”

Principal Investigator: Joseph Terdiman, MD, PhD
Kaiser Permanente Division of Research
Oakland, CA

46. Project No. 02-08-01 (Opton)

Project Title: “Potential Associations among Hospital Financial Status, Patient Insurance Status, Quality of Care and Outcomes for Patients with Cardiovascular Disease”

Principal Investigator: David R. Thiemann, MD
The Johns Hopkins Hospital
Baltimore, MD

47. Project No. 91-08-07 (Lowe)

Project Title: “Smoking as a Risk Factor in the Etiology of Down Syndrome”

Principal Investigator: Claudine Torfs, PhD
Public Health Institute
Emeryville, CA

48. Project No. 03-08-53 (Murphy)

Project Title: “California Injury Surveillance”

Principal Investigator: Roger B. Trent, PhD
DHS
Sacramento, CA

49. Project No. 02-08-07 (Mihordin)

Project Title: “FoodNet Retrospective Cohort Study of the Impact on Clinical Outcome of Salmonella Typhi With Reduced Susceptibility to Fluoroquinolones”

Principal Investigator: Duc Vugia, MD
DHS
Berkeley, CA

50. Project No. 99-08-06 (Opton)

Project Title: “Enhancement of Mandated Surveillance of Communicable Diseases Using California Hospital Discharge Data”

Principal Investigator: Duc Vugia, MD
DHS
Berkeley, CA

51. Project No. 97-08-06 (Snipes)

Project Title: "Epidemiology of Shigellosis in San Francisco"

Principal Investigator: Duc Vugia, MD
DHS
Berkeley, CA

52. Project No. 97-08-02 (Mihordin)

Project Title: "Describing the Population in an Inpatient
Psychiatric Unit within a Correctional Facility"

Principal Investigator: Myla H. Young, PhD
DMH
Vacaville

53. Project No. 02-08-02 (Cordero)

Project Title: "Neighborhood Level Influences on All-cause
Mortality and Morbidity"

Principal Investigator: Marilyn Winkleby, MPH, PhD
Stanford University School of Medicine
Stanford, CA

Continuing Review/With Revisions – Expedited Review

54. Project No. 02-08-05 (Harris) **APPROVED**

Project Title: "Migration and Service Utilization Patterns among California
HIV/AIDS Patients Enrolled in Programs Funded by the
Ryan White CARE Act"

Principal Investigator: Denise Absher
DHS
Sacramento, CA

55. Project No. 03-08-05 (Harris) **APPROVED**

Project Title: "Compliance with California's Non-Name HIV Reporting
System by Health Care Providers and Laboratory Staff"

Principal Investigator: Jennifer Baham, MPH
DHS
Sacramento, CA

56. Project No. 01-08-17 (Murphy)

Project Title: "Children and Families of Incarcerated Women"

Principal Investigator: Henry Brady, PhD
UCB
Berkeley, CA

57. Project No. 00-08-11 (Lowe)

Project Title: "Pregnancy and Pediatric Outcomes Study"

Principal Investigator: Mary Croughan, PhD
UCSF
San Francisco, CA

58. Project No. 00-08-08 (Harris) **APPROVED**

Project Title: "California Intensive Care Outcomes Study (CALICO)"

Principal Investigator: R. Adams Dudley, MD, MBA
UCSF
San Francisco, CA

59. Project No. 03-08-58 (Opton)

Project Title: "The Utility of the HCR-20 in Predicting Outcomes in Restoration of Sanity Hearings in California"

Principal Investigator: Kerry J. Eudy, MA, JD
Pacific Graduate Student of Psychology
Cambridge, MA

60. Project No. 00-08-02 (Lowe)

Project Title: "Replication of Newborn Blood Specimen Proteins in Children with Autism and Mental Retardation"

Principal Investigator: Judith Grether, PhD
DHS
Oakland, CA

61. Project No. 99-08-08 (Lowe)

Project Title: "Environmental Approaches to Prevention Project"

Principal Investigator: Paul Gruenewald, PhD
Prevention Research Center
Berkeley, CA

62. Project No. 88-08-02 (Opton)

Project Title: "California Statewide HIV Seroprevalence Family Surveys"

Principal Investigator: Shulan He, MD, MS
DHS
Sacramento, CA

63. Project No. 89-08-08 (Cordero)

Project Title: "California Pediatric HIV Infection Active Surveillance"

Principal Investigator: Shulan He, MD, MS
DHS
Sacramento, CA

64. Project No. 03-08-06 (Cordero)

Project Title: "Self-Employment Services and Outcomes:
A View of California Vocational Rehabilitation"

Principal Investigator: Kristina Inn, MA
Pacific Basin Rehabilitation
Research and Training Center
Honolulu, HI

65. Project No. 99-08-11 (Mihordin)

Project Title: "Newborn Screening for Cystic Fibrosis in California"

Principal Investigator: Marint Kharrazi, PhD
DHS
Richmond, CA

66. Project No. 03-08-55 (Cordero)

Project Title: "The Effects of Stress and Race-related Stress on
Birth Weight: September 11th"

Principal Investigator: Diane S. Lauderdale, PhD
University of Chicago
Chicago, IL

67. Project No. 01-08-18 (Harris)

Project Title: "Indicators of Maternal Quality of Care for the State of California"

Principal Investigator: Michael C. Lu, MD, MPH
UCLA
Los Angeles, CA

68. Project No. 03-08-04 (Opton)

Project Title: "Surveillance of HIV Risk & Prevention Behaviors of Men Who Have Sex With Men; San Diego, California"

Principal Investigator: Assunta Ritieni, MHS
DHS
Sacramento, CA

69. Project No. 00-08-07 (Mihordin)

Project Title: "Survey of HIV Seroprevalence, Markers for Hepatitis and Sexually Transmitted Diseases, and Assessment of Associated Risk Behaviors in Young Men Residing in Low-Income Neighborhoods in Five Northern California Counties"

Principal Investigator: Juan Ruiz, MD, Dr PH
DHS
Sacramento, CA

70. Project No. 01-08-12 (Lowe)

Project Title: "Adult Testicular Cancer Lifestyle and Blood Specimen (ATLAS) Study"

Principal Investigator: Stephen M. Schwartz, PhD
Fred Hutchinson Cancer Research Center
Seattle, WA

71. Project No. 02-06-01 (Lowe)

Project Title: "Early Discharge and Infant Mortality"

Principal Investigator: Neeraj Sood
RAND
Santa Monica, CA

72. Project No. 00-06-08 (Mihordin)

Project Title: "Trisomy 21: Risk Factors for Chromosome Nondisjunction"

Principal Investigator: Claudine P. Torfs, PhD
Public Health Institute
Emeryville, CA

D. Second Review Calendar

1. Project No. 04-06-06 (Kirkish) (2nd mailing)

Project Title: "Partners in Care for Children"

Principal Investigator: Bonnie T. Zima, MD, MPH
UCLA
Los Angeles, CA

E. New Projects Calendar

1. Project No. 04-08-01 (Snipes)

Project Title: "Heat Treatment of Breast Milk to Prevent Mother-to-Child Transmission of HIV"

Principal Investigator: Richard M. Donovan, PhD
DHS
Richmond, CA

2. Project No. 04-08-02 (Lowe)

Project Title: "Environmental Health Specialists Network's Hand Hygiene Study"

Principal Investigator: Michael-Peter A. Esko, REHS
California Emerging Infections Program
Oakland, CA

3. Project No. 04-08-03 (Mihordin)

Project Title: "A California Population-Based Twin Study of Autism"

Principal Investigator: Judith K. Grether, PhD
DHS
Oakland, CA

4. Project No. 04-08-04 (Murphy)

Project Title: "The Experiences of Long Term HIV/AIDS Survivors:
Changes & Challenges"

Principal Investigator: Pamela Johansen, EDD, LCSW
Home Health Care Management, Inc.
Chico, CA

5. Project No. 04-08-05 (Harris)

Project Title: "Integration of Newborn Public Health Information Systems"

Principal Investigator: Marin Kharrazi, PhD
DHS
Richmond, CA

6. Project No. 04-08-06 (Opton) (2nd mailing)

Project Title: "Air Pollution and Cardiovascular Disease in the
California Teachers Study Cohort"

Principal Investigator: Michael Lipsett, PhD, MD, JD
DHS
Oakland, CA

EE. New Projects – Expedited Review

1. Project No. 04-08-51 (Lubeck)

Project Title: "Evaluating and Improving the CHIS Data"

Principal Investigator: Jacob Alex Klerman, PhD
RAND
Santa Monica, CA

2. Project No. 04-08-52 (Lubeck)

Project Title: "Medi-Cal Take-Up Among Welfare Leavers, Revisited"

Principal Investigator: Jacob Alex Klerman, PhD
RAND
Santa Monica, CA

3. Project No. 04-08-53 (Murphy)

Project Title: "Racial Differences and Trends in Fertility-Stopping
Decisions, and Prenatal Care"

Principal Investigator: Jason Abrevaya, PhD

Purdue University
West Lafayette, IN

4. Project No. 04-08-54 (Opton) **APPROVED**

Project Title: "Validation of Payer and Health Plan Information for
Medi-Cal Beneficiaries in Patient Discharge Data
1998-2002"

Principal Investigator: Andrew B. Bindman, MD
UCSF
San Francisco, CA

5. Project No. 04-08-55 (Kirkish)

Project Title: "Newborn Protein Markers for Childhood Autism"

Principal Investigator: Judith K. Grether, PhD
DHS
Oakland, CA

6. Project No. 04-08-56 (Harris)

Project Title: "A Study of Met and Unmet Need for Developmental
Disability Services in California"

Principal Investigator: Charlene Harrington, PhD
UCSF
San Francisco, CA

7. Project No. 04-08-57 (Ruiz)

Project Title: "Infectious Diseases Related to Hospitalization of
Children in California"

Principal Investigator: Yvonne Maldonado, MD
Stanford University
Stanford, CA

8. Project No. 04-08-58 (Mihordin)

Project Title: "California Coronary Artery Bypass Graft Outcome
Reporting Program (CCORP)"

Principal Investigator: Joseph P. Parker, PhD
OSHPD
Sacramento, CA

9. Project No. 04-08-59 (Snipes)

Project Title: "An Epidemiologic Investigation of Tuberculosis
Reactivation –San Francisco, 1985-2003"

Principal Investigator: Travis Porco, PhD
DHS
Berkeley, CA

10. Project No. 04-08-60 (Ko)

Project Title: "Cost-effectiveness of Rehabilitation Stays"

Principal Investigator: Keith V. Kuhlemeier, PhD, MPH
The Johns Hopkins University School of Medicine
Baltimore, MD

F. Other Business, Information, and Items of Discussion

1. Adverse Event Reports - None
2. Completed Projects

a. Project No. 85-08-06 (Murphy)

Project Title: "The Sex Offender Treatment and Evaluation Project"
Principal Investigator: Janice Marques, PhD
DMH
Sacramento, CA

3. Projects Withdrawn by Principal Investigator

a. Project No. 02-04-10 (Murphy)

Project Title: "Violence in Forensic and Non-Forensic Patients"
Principal Investigator: Anne L. Hoff, PhD
UC Davis-Napa Psychiatric Research Center
Napa, CA

b. Project No. 01-08-15 (Mihordin)

Project Title: "Use of the Thematic Apperception Test with Schizophrenic
Patients: The Utility of Employing Prompts"
Principal Investigator: Lawrence Ledesma, PhD
DMH Metropolitan State Hospital
Norwalk, VA

c. Project No. 03-08-52 (Harris)

APPROVED

Project Title: "Models of Birthweight and Low Birthweight"
Principal Investigator: Narayan Sastry, PhD
RAND
Santa Monica, CA

4. Projects Terminated by CPHS – None
5. Exemption Requests since last meeting
Approved - None
Denied - None
6. Expedited Reviews approved since last meeting

Project No: 04-06-51
Project Title: "Risk Adjustment Research"

Project No: 01-12-15
Project Title: "Assessment of Mental Illness, Violence Risk and Readiness for Release in a Forensic Facility"

Project No: 99-12-09
Project Title: "Evaluating the Effects of Air Pollution Exposures on Adverse Birth Outcomes in Southern California"

Project No: 04-02-05
Project Title: "Enhanced Surveillance to Identify Missed Opportunities for Prevention of Tuberculosis in the Foreign-born"

Project No: 04-04-04
Project Title: "Healthy Women Project"

Project No: 03-12-50
Project Title: "RSV Admissions and Readmissions in Children"

Project No: 96-04-02
Project Title: "Xenoestrogens and Breast Cancer in African American Women"

Project No: 01-10-12
Project Title: "The California Unexplained Pneumonia Project (CUPP): Diagnostic Evaluation of Acute Pulmonary Syndrome"

Project No: 04-04-06
Project Title: "Exploring Early Detection Methods: Using the Intraductal Approach to Predict Breast Cancer"

Project No: 02-12-08
Project Title: "Adult Males' Perceptions of Children's Likeability"

7. Continuing Education Materials – Available at meeting

G. Next Meeting

Scheduled for October 1, 2004 in Sacramento.

H. Adjournment

*Pursuant to the Americans with Disabilities Act, the Committee for the Protection of Human Subjects will make reasonable effort to accommodate persons with disabilities. For special accommodations, please contact the Committee at least five working days in advance of the meeting.

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